ANNEX IIIB

PACKAGE LEAFLET: INFORMATION FOR THE USER

Name of the medicinal product

ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE, oral suspension in multidose container

Boxed text

Read all of this leaflet carefully before vaccination

- Keep this leaflet, you may need to read it again.
- If you have further questions, if you have a doubt, please ask your doctor or pharmacist for more information.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

Package Leaflet summary

In this leaflet:

1. WHAT ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE, oral suspension in multidose container IS AND WHAT IS USED FOR

Pharmacotherapeutic group

This medicinal product is a vaccine. Vaccines are used to protect against infectious diseases. When this vaccine is administered by oral route, the body's natural defenses develop a protection against those diseases.

Therapeutic indications

ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE is indicated in all age groups for primary vaccination and reinforcement of the immunity against poliomyelitis caused by types 1 and 3 polioviruses.

The use of this vaccine should be in accordance with official recommendations.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE, oral suspension in multidose container

List of information necessary before taking the medicinal product

Not applicable.

Contraindications

Do not use ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE in case of :

- allergy (hypersensitivity)
  - to any component of the vaccine (listed in Section 6 – Further information),
  - to neomycin, streptomycin or polymyxin B (used during manufacturing and which may be present as traces)
- severe reactions after previous administration of an oral poliomyelitis vaccine.

- close contact with patients having immune deficiency.
- Primary immune deficiency or immune deficiency subsequent to treatment, leukaemia, lymphoma or advanced malignancy.
  Patients with asymptomatic human immunodeficiency virus (HIV) infection should be vaccinated according to the WHO official recommendations.

Precautions for use; special warnings

Warnings and precautions for use

- In the event of vomiting after administration of a dose , a second dose may be given after the symptoms have disappeared.
- In the event of fever or acute disease, it may be recommended to postpone vaccination according to national policy.
- After vaccination, polioviruses are excreted by vaccinees and may contaminate contact persons, including pregnant or breast-feeding women. The safety of the ORAL BIVALENT TYPE 1 and 3 POLIOMYELITIS VACCINE in pregnant or breast-feeding women is not known. Clinical and epidemiological studies have not revealed any congenital malformations or foetotoxic effects related to the oral poliomyelitis vaccine in exposed pregnant women.
- In premature or low birth weight infants, vaccination must be performed at chronological age, without correction related to duration of pregnancy (gestational age) or birth weight.

This vaccine must not be injected.

Interactions with other medicinal products

Other medicines and ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE:

ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE may be given concomitantly during the same vaccination session with injectable inactivated vaccines such as diphtheria, tetanus, pertussis (acellular whole cell) vaccines, the inactivated poliomyelitis vaccine, the *Haemophilus influenzae* type b conjugate vaccine, hepatitis A vaccines and hepatitis B vaccines, pneumococcal conjugate vaccines and with live attenuated vaccines such as measles, rubella, mumps and yellow fever vaccines.

Concomitant administration of the oral poliomyelitis vaccine decreases the immune response to the rotavirus vaccine. However, there is currently no evidence that clinical protection against severe gastroenteritis is modified.

Interactions with food and drinks

Not applicable.

Interactions with phytotherapy or alternative therapies

Not applicable.

Use during pregnancy and breast-feeding

Pregnancy and breast-feeding

Data on the use of this vaccine in pregnant women are limited.

ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE should be given to pregnant women only if clearly needed and following an assessment of the risks and benefits.

Breast-feeding is not a contraindication.

Athletes

Not applicable.

Effects on the ability to drive or to use machines

Driving and using machines

The ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE is not expected to have influence on the ability to drive and use machines..

List of Excipients with recognised effect

Not applicable.

3. HOW TO USE ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE, oral suspension in multidose container

Instruction for proper use

This vaccine will be administered by a healthcare professional

Dosage, Method and/or route(s) of administration, Frequency of administration and Duration of treatment

Dosage

The vaccine dose is 2 drops (0.1 ml) measured using the multi-dose dropper.

The vaccinating dose can be administered directly in the mouth or on a sugar lump.

If a dropper is used, care must be taken not to contaminate the dropper with the saliva of the vaccinee.

Method of administration

The vaccine must only be administered orally.

Frequency of administration

Primary vaccination or booster doses should be given in accordance with official recommendations.

Symptoms in case of overdose and actions to be taken

If you use more ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE than you should:

Few cases of overdose have been reported. No particular actions are to be put in place in case of overdose because the side effects are those described in Section 4.

Actions to be taken when one or more doses have been missed

Not applicable.

Risk of withdrawal syndrome

Not applicable.

4. POSSIBLE SIDE EFFECTS

Description of side effects

Like all medicine, this vaccine can cause side effects although not everybody gets them.

Since Oral Bivalent Types 1 and 3 Poliomyelitis Vaccine contains two of the three components of the oral trivalent poliomyelitis vaccine, its safety profile is close to the oral trivalent poliomyelitis vaccine safety profile.

- In exceptional cases, Vaccine Associated Paralytic Poliomyelitis (VAPP) due to the reversion of the vaccine virus to neurovirulence may be observed. VAPP may exceptionally present as transverse myelitis. These VAPP cases occur within 4 to 8 weeks following the vaccination. The majority of VAPP cases occur after the first dose.
  The overall incidence of this type of event varies from one case per 1.4 to 2.8 million vaccinees with the use of an oral trivalent poliomyelitis vaccine. As most cases of VAPP are due to type 2 vaccine poliovirus, the frequency expected with ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE is lower.
- Myalgia (muscle pain) and arthralgia (joint pain).
- General reactions: fever, rigors, asthenia (tiredness)

5. HOW TO STORE ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE, oral suspension in multidose container

Keep this medicine out of the sight and reach of children.

Expiry date

Do not use ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE after the expiry date which is stated on the label, the box.

The expiry date refers to the last day of that month.

Storage conditions

Store in a freezer (-20°C).

After thawing, the product can be stored for 6 months in a refrigerator (between 2°C and 8°C).

Vaccine Vial Monitors (VVM)

✓ Inner square lighter the outer circle. **If the expiry date has not been passed, USE the vaccine.**

✘ Discard point: **Inner square matches colour of outer circle. DO NOT USE the vaccine.**

✘ Beyond the discard point: **Inner square darker than outer circle. DO NOT USE the vaccine.**

The Vaccine Vial Monitors (VVMs) are on the label of ORAL BIVALENT TYPES 1 AND 3 POLIOMYELITIS VACCINE supplied through WHO.

The colour dot which appears on the label of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.

The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the circle, then the vaccine can be used. As soon as the colour of the central square is the same colour as the circle or of a darker colour than the circle, then the vial should be discarded.

Where appropriate, warning against certain visible signs of deterioration

Not applicable.

6. FURTHER INFORMATION

Full statement of active substances and excipients

What ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE contains

- The active substance is:

Poliomyelitis virus type 1*, LS - c2ab strain, (live, attenuated) at least 6.0 $\log^{\dagger}$ $CCID_{50}^{\ddagger}$

Poliomyelitis virus type 3*, Leon - 12a1b strain, (live, attenuated) at least 5.8 $\log^{\dagger}$ $CCID_{50}^{\ddagger}$

For each 0.1-mL dose (2 drops)

* Produced in Vero cells
† Previously expressed as "at least 10^{x} $CCID_{50}$"
‡ $CCID_{50}$: 50% Cell Culture Infective Doses (viral infectious units).

- The other ingredients are:

Human albumin, HEPES buffer solution, magnesium chloride solution (containing polysorbate 80 and phenol red).

The vaccine fulfils the WHO requirements.

Pharmaceutical form and contents

What ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE looks like and contents of the pack

This vaccine is an oral suspension in a multidose vial (2-mL vial – 20 doses of 0.1 mL) – Box of 10 vials.

Name and address of the marketing authorisation holder and the manufacturing authorisation holder responsible for batch release, if different

Marketing authorisation holder
SANOFI PASTEUR LTD. - Bangkok, Thailand

Name of the medicinal product in the Member States of the European Economic Area

Not applicable.

Date of approval of the package leaflet

This leaflet was last revised on 08/2015.

Marketing authorisation under exceptional circumstances

Not applicable.

Internet information

Detailed information on this medicinal product is available on the Internet site of Ansm (France), www.ansm.sante.fr.

Information intended for healthcare professionals

The following information is intended for healthcare professionals only:

The vial must be shaken gently to avoid any foaming, but sufficiently to obtain a homogenous mixture of the contents.

Obtaining one or several vaccine doses out of one multidose vial essentially depends on the care of handling.

After first and any subsequent opening, the multidose vial should be kept between 2°C and 8°C.

Multi-dose vials from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions in compliance with the WHO Multi-Dose Vial Policy.

The vaccine must be administered exclusively by the oral route.

After use, remaining vaccine, vials and also spoons should be disposed of safely, preferably by heat inactivation or incineration, according to locally agreed procedures.

Other

Not applicable.